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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,756

12/21/2005

Richard E Musty

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,756	Applicant(s) MUSTY ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-15, 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2008 has been entered.

Response to Arguments

Applicants present arguments and a Declaration (presented by Dr. Whittle) to rebut the 35 USC 103 rejection over Brooke et al. in view of Travis and Turner. The arguments presented by Applicant and the arguments presented in the Declaration overlap and both will be addressed accordingly. Applicants argue that the teachings of Brooke et al. were misconstrued and Dr. Whittle is of the opinion that one of ordinary skill in the art would most likely attribute the beneficial activities of cannabis to either THC and/or CBD. Dr. Whittle further argues that the listing of medicinal uses of cannabis and the active ingredients of cannabis are two distinct statements and they should not be combined. Dr. Whittle also argues that one of ordinary skill in the art would be well aware that cannabis is also considered, by many, to be responsible for causing depression; therefore, leading one to not use a cannabinoid in the treatment of mood disorders.

In response to the above arguments, the teachings of Brooke et al. have not been misconstrued. Brooke et al. clearly makes a connection between the medicinal uses of cannabis and the active ingredients in cannabis. The sentence in Col. 1, beginning at line 24 states that "several medicinal uses have been found for the active ingredients of cannabis, including the ingredients tetrahydrocannabinol (THC), cannabinol (CBN), cannabidiol (CBD) and cannabichromene (CBC). The medicinal uses of cannabis include.....(8) stress and depression....". From this statement alone it is clear that CBC is an active ingredient of cannabis that contributes to the medicinal effects of which include stress and depression. Regarding Dr. Whittle's opinion that many consider cannabis to be responsible for depression, this statement has no conclusory evidence to verify this. A scan through the literature shows that this is an unfounded conclusion and has no substantial evidence to credit that statement.

Dr. Whittle further argues that one would have concentrated on the primary cannabinoids THC and CBD and not a minor cannabinoid such as CBC since it is only found in small quantities in mature plants (referring to the articles previously presented by Vogelmann et al., Rowan and Fairbairn). Dr. Whittle further argues that one would be aware that cannabis is also considered by many to be responsible for causing depression. While the Examiner recognizes that Vogelmann et al., Rowan and Fairbairn may concentrate on THC being the major cannabinoid, there is also evidence that CBC, in some drug strains of the plant CBC has been reported as the second most abundant cannabinoid (first paragraph on page 275; Harvey et al., Biol Mass Spec, Vol. 20, 275-285, 1991). Further, Turner et al. teaches that different strains have different

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amounts of cannabichromene with some having more than others and states that CBC is one of the most abundant naturally occurring cannabinoids and further states that in freshly harvested drug-type cannabis material, THC and CBC are the major cannabinoids. Therefore, different strains have different amounts of CBC with some obviously having more than others. It cannot be concluded that CBC is a minor part of all plants and would not be expected to have any medicinal properties. Further there is evidence (in the following rejections) to the contrary of the assertion that cannabis causes depression and because this opinion is unfounded the following rejections are being given below.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15, 18-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,51) and Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Brooke et al. teach that medicinal uses, such as depression, have been found for the active ingredients of cannabis, including cannabichromenes (meeting the limitation of claims 14-15; Col. 1, lines 23-33).

Brooke et al. does not teach a cannabichromene compound of the same structural formula as Formula (I) in claims 14 and 20-24, that the cannabichromene compound is an extract of at least one cannabis plant as claimed in claims 18 and 25-27 or the route of administration.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds of the general formula (I), wherein R^1 is OH, R^2 is H, R^3 is a C_{5-12} alkyl, Q is O, R^6 is C_{1-6} alkyl, and R^{12} and $R^{12'}$ are C_{1-6} alkyl (meeting the limitations of claims 1 and 20-24; Col. 2, lines 21, 25, 55-56; Col. 3, lines 24, 35, 39, 64; Col. 4, line 2). The compositions are further obvious over general formula (I) when R^3 is C_3H_7 of claims 20-21 because the difference between C_3H_7 and C_5H_{11} (as taught by Travis) differ in only two carbons and are considered analogous over each other. Travis further teaches that the alkyl groups of R_3 can be straight chained (meeting the limitations of claim 22; paragraph 0102). Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression. It would have further been obvious to use the cannabichromene composition taught by Travis and

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Turner et al. to treat depression, because Travis and Turner et al. teach cannabichromene compositions that are useful as pharmaceutical compositions. One would have been motivated to use the cannabichromene compositions taught by Travis and Turner et al. to treat depression with a reasonable expectation of success because Brooke et al. teaches that cannabichromenes show medicinal use in treating depression.

Claims 14-15, 18-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle and al. (US Pg/Pub 2005/0042172) in view of Travis (US Patent 6,541,51).

Whittle et al. teaches therapeutic compositions that are inhaled as a vapour (paragraph 0030) that comprise one or more natural or synthetic cannabinoids, which includes cannabichromene (paragraphs 0049 and 0051). It is further taught that the compositions that contain natural cannabinoids which are derived from cannabis plants (paragraphs 0042, 0043 0053). The compositions are taught to comprise carriers or solvents (paragraph 0072). The compositions are used in methods of treating inflammatory pain particularly that associated with depression (paragraph 0056), in which it is considered that the composition would necessarily be treating depression.

Whittle et al. does not teach a cannabichromene compound of the same structural formula as Formula (I) in claims 14 and 20-24.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds of the general formula (I), wherein R^1 is OH, R^2 is H, R^3 is a C_{5-12} alkyl, Q is O, R^6 is C_{1-6} alkyl, and R^{12} and $R^{12'}$ are C_{1-6} alkyl (meeting the limitations of claims 1 and

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20-24; Col. 2, lines 21, 25, 55-56; Col. 3, lines 24, 35, 39, 64; Col. 4, line 2). The compositions are further obvious over general formula (I) when R^3 is C_3H_7 of claims 20-21 because the difference between C_3H_7 and C_5H_{11} (as taught by Travis) differ in only two carbons and are considered analogous over each other. Travis further teaches that the alkyl groups of R_3 can be straight chained (meeting the limitations of claim 22; paragraph 0102). Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Whittle et al. that cannabichromenes are useful in treating such disorders as pain associated with depression. It would have further been obvious to use the cannabichromene composition taught by Travis to treat depression, because Travis teaches cannabichromene compositions that are useful as pharmaceutical compositions. One would have been motivated to use the cannabichromene compositions taught by Travis to treat depression with a reasonable expectation of success because Whittle et al. teaches that cannabichromenes show medicinal use in treating pain associated with depression, which would necessarily treat depression.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim s 14-15, 18-25, 27-28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 12, 14 of copending Application No. 11/760,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach methods of treating a mood disorder with a naturally occurring cannabinoid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617